NOV 2 4 2003

K032598

Attachment 2

510(k) Summary

Company:	Synergetics, Inc. 3845 Corporate Centre Drive St. Charles, MO 63304
Contact Person:	Dan Regan
Date:	October 21, 2003
Trade Name:	Synergetics Synerlight FiberOptic Lightsource
Common Name:	Ophthalmic Fiberoptic Lightsource
Predicate Device:	K964005
Description/Intended Use:	The intended use of the device is to illuminate the eye during anterior and posterior vitreoretinal surgery and to provide photocoagulation when used with the appropriate commercially available laser light source and probe.
Testing Summary:	Testing demonstrated that the subject device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2003

Mr. Dan Regan
Quality Assurance/Regulatory Affairs Director
Synergetics, Inc.
3845 Corporate Centre Drive
St. Charles, Missouri 63304

Re: K032598
Trade/Device Name: Synergetics Synerlight FiberOptic Lightsource
Regulation Number: 21 CFR 876.1500, 878.4810
Regulation Name: Endoscope and accessories, Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: MPA, GEX
Dated: August 22, 2003
Received: August 26, 2003

Dear Mr. Regan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known)	K032598
Device Name	Synergetics Synerlight FiberOptic Lightsource
Indications for Use	The intended use of the device is to illuminate the eye during anterior and posterior vitreoretinal surgery and to provide photocoagulation when used with the appropriate commercially available laser light source and probe.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use ____
(per 21 CFR 801.109)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K032598